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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/696,676 10/29/2003		Keith L. Black	67789-503	8501		
50670	7590 06/28/2006			EXAMINER		
DAVIS WR	JGHT T	REMAINE LLP	SCHNIZER, RICHARD A			
865 FIGUER	OA STR	EET				
SUITE 2400			ART UNIT	PAPER NUMBER		
LOS ANGEL	FS CA	90017-2566	1635			

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	No.	Applicant(s)	
	10/696,676		BLACK ET AL.		
Office Action Sur	Examiner	· · · · · · · · · · · · · · · · · · ·	Art Unit	Γ	
		Richard Schr	izer, Ph. D	1635	
- The MAILING DATE of the	nis communication app	1		1	ddress
Period for Reply					
A SHORTENED STATUTORY WHICHEVER IS LONGER, FR - Extensions of time may be available undurafter SIX (6) MONTHS from the mailing of lf NO period for reply is specified above, Failure to reply within the set or extended Any reply received by the Office later than earned patent term adjustment. See 37 (COM THE MAILING DA er the provisions of 37 CFR 1.13 late of this communication. the maximum statutory period w d period for reply will, by statute, in three months after the mailing	ATE OF THIS 36(a). In no event, will apply and will ex , cause the applicat	COMMUNICATION however, may a reply be tin spire SIX (6) MONTHS from ion to become ABANDONE	N. nely filed the mailing date of this (D (35 U.S.C. § 133).	
Status					
1) Responsive to communic	cation(s) filed on 02 M	lay 2006			
2a) This action is FINAL .		action is non	-final		
3) Since this application is i	,			osecution as to th	e merits is
closed in accordance wit		•	· ·		0 1110/110 10
Disposition of Claims		,			
4)⊠ Claim(s) <i>1 and 110-203</i> i	is/are pending in the a	nnlication			
4a) Of the above claim(s)	•	• •	99 is/are withdrawn	from considerati	on:
5) Claim(s) is/are all		oo ana joz i	<u>50</u> 10/010 William		
6) Claim(s) 184,185,187,19		rejected			
7) Claim(s) is/are ob		rejected.			
8) Claim(s) are subjection	•	r election real	iirement		
	sol to restriction and/or	r cicolion requ	momont.		
Application Papers		•			
9)☐ The specification is objec	ted to by the Examine	r.			
10)⊠ The drawing(s) filed on 2	9 October 2003 is/are:	: a)⊠ accept	ed or b)⊡ objected	I to by the Examir	ner.
Applicant may not request t	hat any objection to the	drawing(s) be I	ield in abeyance. Se	e 37 CFR 1.85(a).	
Replacement drawing shee	t(s) including the correcti	ion is required	if the drawing(s) is ob	jected to. See 37 C	FR 1.121(d).
11)☐ The oath or declaration is	s objected to by the Ex	aminer. Note	the attached Office	Action or form P	TO-152.
Priority under 35 U.S.C. § 119					
12) ☐ Acknowledgment is made a) ☐ All b) ☐ Some * c) ☐	None of:)-(d) or (f).	
<u> </u>	the priority documents				
<u> </u>	the priority documents				
·	fied copies of the prior	-		ed in this Nationa	l Stage
, ,	e International Bureau	-			
* See the attached detailed	Office action for a list	of the certified	d copies not receive	ed.	
					,
Attachment(s)				•	
1) Notice of References Cited (PTO-89		4)	☐ Interview Summary	(PTO-413)	
Notice of Draftsperson's Patent Draw	ving Review (PTO-948)		Paper No(s)/Mail Da	ate	O 152)
 Information Disclosure Statement(s) Paper No(s)/Mail Date <u>10/29/03</u>. 	(PTO-1449 or PTO/SB/08)		Notice of Informal F Other:	atent Application (PT	

DETAILED ACTION

An amendment was received and entered on 5/2/06. Applicant's election without traverse of group II and the species of IL-2 is acknowledged. Applicant asserts that this species reads on claims 168-176, 184, 187, 191, and 200-203. However, claims 168-176 are drawn to compositions comprising a combination of an agonist of a calcium-activated potassium channel, other than bradykinin or a bradykinin analog, formulated together with a cytotoxic agent. IL-2 is not a cytotoxic agent. IL-2 is a cytokine that mediates proliferation of cells, among them cytotoxic T-cells, but it is not itself cytotoxic. As a result IL-2 does not read on claims 168-176, but instead reads on claims 184, 185, 187, and 191 which are drawn to a composition comprising a drug and a calcium-activated potassium channel agonist. Claims 200-203 do not recite or require any cytotoxic agent or drug, so the species election is not be applied to these claims.

Claims 1, 110-183, 186, 188-190, and 192-199 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/2/06.

Claims 184, 185, 187, and 191, and 200-203 are under consideration in this Office Action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35

U.S.C. 120 as follows: Although the transmittal letter filed 10/29/03 makes clear that this application is a continuation of 09/491,500, the preliminary amendment filed 10/29/03 claiming priority to 09/491,500 does not state the relationship between the two applications. The first line of the specification should be amended to make clear the relationship between the two applications. Also, the status of 09/491,500 should be updated because it has issued as US Patent 7,018,979.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 184, 185, 187, and 191 are rejected under 35 U.S.C. 102(b) as being anticipated by Novogrodsky et al (J. Imunol. 143: 3981-3987, 1989).

Novogrodsky taught a culture of peripheral blood mononuclear cells comprising IL-2 and either Zn protoporphyrin or Sn protoporphyrin. See abstract, sentence bridging columns 1 and 2 on page 3982, page 3983, column 2, third full paragraph, Table II on page 3984, and Tables IV and V on page 3985. These protoporphyrins are considered to be calcium-activated potassium channel agonists in view of the specification as filed. See e.g. instant claim 175 The culture media is considered to be pharmaceutically acceptable solution. Absent evidence to the contrary, these cultures are in a form that could be injected or infused intravascularly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 200 and 201 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veltkamp et al (Stroke 29: 837-843, 1998).

Veltkamp taught methods of assaying the effects of NS-1619 on the vascular response to NMDA after hypoxia and ischemia. See abstract.

Veltkamp did not teach the organization of NS-1619 and NMDA into a kit.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize these agents into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

The text of Veltkamp, could be considered to be instructions for how to use the kit. However, it is noted that the "instructions for use" limitation does not receive patentable weight because the courts have repeatedly found that the application of particular printed matter to an old article cannot render the article patentable. For example, in the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "[w]hether the statement of intended use appears merely in the claim or in a label

on the product is immaterial so far as the question of patentability is concerned." The court in *In re Gulack* (217 USPQ 401 (1983)) found that printed matter has no patentable weight unless the printed matter affects the function of the product claimed. Also, see in *In re Ngai* (70 USPQ2D 1862 (2004)).

Claims 200 and 202 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devor et al (Am. J. Physiol. 271(5): L775-84, 1996).

Devor evaluated the effects of 1-EBIO and charybdotoxin on chloride ion secretion in T84 monolayers. See abstract.

Devor did not teach the organization of 1-EBIO into a kit. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize these agents into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

The text of Devor could be considered to be instructions for how to use the kit. However, it is noted that the "instructions for use" limitation does not receive patentable weight because the courts have repeatedly found that the application of particular printed matter to an old article cannot render the article patentable. For example, in the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "[w]hether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The court in *In re Gulack* (217 USPQ 401 (1983)) found that printed matter has no patentable weight

unless the printed matter affects the function of the product claimed. Also, see in In re Ngai (70 USPQ2D 1862 (2004)).

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Claims 200 and 203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novogrodsky et al (J. Imunol. 143: 3981-3987, 1989).

Novogrodsky taught a culture of peripheral blood mononuclear cells comprising IL-2 and either Zn protoporphyrin or Sn protoporphyrin. See abstract, sentence bridging columns 1 and 2 on page 3982, page 3983, column 2, third full paragraph, Table II on page 3984, and Tables IV and V on page 3985. These cultures are considered to be pharmaceutical compositions because they comprise all of the structural features of the claims. Absent evidence to the contrary, these cultures are in a form that could be injected or infused intravascularly.

Novogrodsky did not teach the organization of IL-2 and Zn protoporphyrin or Sn protoporphyrin into a kit. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize the IL-2 and Zn protoporphyrin or Sn protoporphyrin of Novogrodsky into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

The text of Novogrodsky, could be considered to be instructions for how to use the kit. However, it is noted that the "instructions for use" limitation does not receive patentable weight because the courts have repeatedly found that the application of particular printed matter to an old article cannot render the article patentable. For

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Art Unit: 1635

example, in the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "[w]hether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The court in *In re Gulack* (217 USPQ 401 (1983)) found that printed matter has no patentable weight unless the printed matter affects the function of the product claimed. Also, see in *In re Ngai* (70 USPQ2D 1862 (2004)).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.

Primary Examiner Art Unit 1635